

### **REMARKS**

Claims 30 and 38-50 remain in the present application. Claims 30 and 38 are the only claims in independent form. Claims 22-24 and 31-33 have been canceled, without prejudice, in order to expedite the allowance of the present application.

Applicants express their gratitude for courtesies extended by the Examiner during a personal interview conducted February 26, 2004, with Applicants' representatives. During the interview, the rejections of record were discussed along with proposed amendments to the claims.

Specifically referring to the Office Action, the drawings of the present application have been objected to under 37 CFR § 1.84. In response thereto, Applicants enclose herewith a replacement drawing for Figure 1. Reconsideration of the objection is respectfully requested.

The specification has been objected to with regard to the claim section. In response thereto, the claims section includes the phrase "What is claimed is:" and therefore, no longer contains the informality. Reconsideration of the objection is respectfully requested.

Claims 22-24, 30-33, and 38-50 have only been examined to the extent that they read on the elected invention of SEQ ID No: 1 corresponding to plasmid pGTE #2, Accession No. NM00/16477. Therefore, the Office Action advises to amend the presently pending claims to be directed towards the elected invention of SEQ ID No: 1 corresponding to plasmid pGTE #2, Accession No. NM00/16477. In response thereto, the presently pending claims have been amended in accordance with the suggestion set forth in the outstanding Office Action.

Claims 22-24, 30-33, and 38-50 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in a manner to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the present invention. More specifically, the Examiner holds that the specification lacks complete information as to how to make the claimed plasmid. However, the Examiner holds that this rejection can be overcome by certifying that the deposits comply with the criteria set forth in 37 CFR § 1.801-1.809. In response thereto, Applicants assert that the plasmids have been deposited and accepted in an International Depository Authority (IDA) under the Budapest Treaty. More specifically, the depository is the Australian Government Analytical Laboratories (AGAL). The deposit was made in compliance with 37 CFR §1.806 and 37 CFR §1.808(a) concerning the term of deposit and permissible conditions on access once the patent is granted. Additionally, all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and the deposit will be replaced if viable samples cannot be dispensed by the depository. Finally, the specification (See, page 2, lines 1-3) sets forth the complete name and full address of the depository. As a result, reconsideration of the rejection is respectfully requested.

Claims 22-24, 30-33, and 39-50 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. According to the Office Action, the specification broadly describes as part of the invention, an isolated nucleotide sequence of SEQ ID No: 1. However, the specification does not teach variants of *Lawsonia intracellularis* encoding a nucleic acid molecule. In response thereto, the presently pending claims have been amended to specifically delete the term “variants.” As a result of the amendment, reconsideration of the rejection is respectfully requested.

Claims 22-24, 30-33, and 39-50 also stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. According to the Office Action, the

present specification is enabled for an isolated *Lawsonia* intracellular vaccine vector comprised in the plasmid pGTE #2flhB or an isolated polynucleotide comprising the nucleotide sequence of SEQ ID No: 1, or an isolated polynucleotide comprising the nucleotide sequence of SEQ ID No: 1 encoding the polypeptide flhB, SEQ ID No: 2. Again, the Examiner holds that the specifications do not enable for any variants of a polynucleotide comprising SEQ ID No: 1. In response thereto, the presently pending claims have been amended and reconsideration of the rejection is respectfully requested.

Claims 22-24 have also been rejected because the specification provides no information on the immunogenicity of the protein encoded by the nucleic acid, the claimed fragments, the variants, or the ability of such to protect from disease. More specifically, the Office Action holds that in the absence of a teaching of the claimed nucleic acids encoding polypeptides can generate an immune response and that the immune response is effective in preventing disease, the specification is not enabled for vaccines. Therefore, in view of the unpredictability of the art, the lack of teachings of the specification, it would require undue experimentation on the part of a skilled artist and to practice the claimed invention. In response thereto, claims 22-24 have been canceled without prejudice and reconsideration of the rejection is respectfully requested.

Claims 22-24, and 31-33 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. More specifically, claims 22 and 33 stand rejected as being vague for the recitation of “a protein encoding nucleic acid sequence.” According to the Office Action, a protein is generally encoded by a nucleic acid or a nucleic acid encodes a protein. In response thereto, the presently pending claims 22 and 33 have been canceled without prejudice. Reconsideration of the rejection is respectfully requested.

Additionally, claims 22 and 31 stand rejected as being vague for the recitation of the phrase "low stringency." In response thereto, these claims have been amended and reconsideration of the rejection is respectfully requested. Finally, claims 22 and 31 stand rejected as being vague for the recitation of the terms "homologue," "analog," and "derivative." In response thereto, the definitions of these terms can be found on page 44, lines 8-16, and page 31, line 31 to page 34, line 23. Reconsideration of the rejection is respectfully requested.

In summary, the presently pending application is now in condition for allowance, which allowance is respectfully requested. If any remaining issues exist, Applicants respectfully request to be contacted by telephone at (248) 539-5050.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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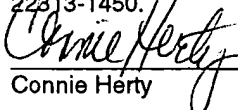
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